

DIPHENHYDRAMINE HCL- diphenhydramine hcl tablet, coated
Rugby Laboratories

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Rugby 44-329

Active ingredient (in each tablet)

Diphenhydramine HCl 25 mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - runny nose
 - itchy, watery eyes
 - sneezing
 - itching of the nose or throat
- temporarily relieves these symptoms due to the common cold:
 - runny nose
 - sneezing

Warnings

Do not use

- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic beverages

- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away

Directions

- **do not take more than directed**
- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours

| | |
|---|-------------------|
| adults and children 12 years and over | 1 to 2 tablets |
| children 6 to under 12 years | 1 tablet |
| children under 6 years | do not use |

Other information

- **each tablet contains:** calcium 30 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from moisture
- use by expiration date on package

Inactive ingredients

corn starch, D&C red #27 aluminum lake, dibasic calcium phosphate dihydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

(800) 645-2158

Principal display panel

Rugby®

NDC 0536-1214-29

Compare to the active
ingredient in Benadryl®
Allergy ULTRATAB® Tablets*

Diphenhydramine HCl
25 mg

Antihistamine /Allergy Relief

Relieves Sneezing,
Runny Nose, Itchy throat
and Itchy, Watery Eyes

100 Tablets

Actual Size

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

*This product is not manufactured or distributed by Johnson & Johnson Corporation,
owner of the registered trademark Benadryl® Allergy ULTRATAB® Tablets.

50844 REV1220A32912

Distributed by: RUGBY® LABORATORIES

Livonia, MI 48152

www.rugbylaboratories.com

Rev.03/21

R-17

Re-order No. 370672

Drug Facts (continued)
Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product

- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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Inactive ingredients corn starch, D&C red #27 aluminum lake, dibasic calcium phosphate diphosphate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments? (800) 645-2158

STOP PEELING



NDC 0536-1214-29
Compare to the active ingredient in Benadryl® Allergy ULTRATAB® Tablets*

Diphenhydramine HCl

25 mg

Antihistamine/Allergy Relief

Relieves Sneezing, Runny Nose, Itchy Throat and Itchy, Watery Eyes

Actual Size

100 Tablets

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING


Drug Facts

| | |
|---|---------------------------------|
| Active ingredient (in each tablet) Diphenhydramine HCl 25 mg | Purpose Antihistamine |
| Uses <ul style="list-style-type: none">temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:<ul style="list-style-type: none">runny noseitchy, watery eyessneezingitching of the nose or throattemporarily relieves these symptoms due to the common cold:<ul style="list-style-type: none">runny nosesneezing | |
| Warnings <ul style="list-style-type: none">Do not usewith any other product containing diphenhydramine, even one used on skin | |
| Ask a doctor before use if you have <ul style="list-style-type: none">a breathing problem such as emphysema or chronic bronchitisglaucomadifficulty in urination due to enlargement of the prostate gland | |

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Livonia, MI 48152
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Rev. 03/21
R-17
Re-order No. 370672



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PEEL HERE FOR MORE DRUG FACTS

44-329

DIPHENHYDRAMINE HCL

diphenhydramine hcl tablet, coated

| Product Information | | | |
|--|----------------|-------------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0536-1214 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII: 8GTS82S83M) | | DIPHENHYDRAMINE HYDROCHLORIDE | 25 mg |
| Inactive Ingredients | | | |
| Ingredient Name | | | Strength |
| STARCH, CORN (UNII: O8232NY3SJ) | | | |
| D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX) | | | |

| | |
|---|--|
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP) | |

Product Characteristics

| | | | |
|-----------------|------|---------------------|----------|
| Color | pink | Score | no score |
| Shape | OVAL | Size | 11mm |
| Flavor | | Imprint Code | 44;329 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0536-1214-29 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/28/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 03/28/2019 | |

Labeler - Rugby Laboratories (079246066)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 832867894 | manufacture(0536-1214) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|--|
| LNK International, Inc. | | 868734088 | manufacture(0536-1214) , pack(0536-1214) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 832867837 | pack(0536-1214) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

| | | | |
|-------------------------|--|-----------|-----------------|
| LNK International, Inc. | | 038154464 | pack(0536-1214) |
|-------------------------|--|-----------|-----------------|

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 967626305 | pack(0536-1214) |

Revised: 4/2021

Rugby Laboratories